REMARKS

I. Restriction Requirement to Groups I-IV

The Examiner has restricted the claims into four different groups, including: Group I (Claims 1-3, 7-47 and 49) directed toward methods for detecting a target nucleic acid sequence; Group II (Claims 4-6) directed toward methods for detecting an analyte in a sample; Group III (Claim 48) directed toward methods for selectively transcribing a target molecule; and Group IV (Claims 50-53) directed toward kits for detecting a target nucleic acid. Applicants hereby elect Group I directed toward methods for detecting a target nucleic acid sequence without traverse. It is noted that all of the pending claims (1-53) have been cancelled for business reasons to expedite the prosecution of the present application. New Claims 54-82 have been added. New Claims 54-82 are within Group I, which has been elected.

II. Restriction Requirement to a Single Ligase, a Single RNA Polymerase, and a Single Promoter SEQ ID NO

The Examiner also requested further restriction into the following three sub-groups: 1) a single ligase selected from Claims 32 and 33; 2) a single RNA polymerase selected from Claims 34-36; and 3) a single promoter selected from SEQ ID NOs 16, 19, 27, 28, or 29 (which appear in Claims 30 and 31). In the claims and SEQ IDs cited by the Examiner, there are 6 specific ligases, 7 specific RNA polymerases, and 5 specific promoters. As such, by restricting the claims into 4 main groups, 6 ligase sub-groups, 7 RNA polymerase sub-groups, and 5 promoter sub-groups, the Examiner has effectively issued an 840-way restriction (as 4 x 6 x 7 x 5 = 840). Applicants hereby traverse the sub-group portion of this onerous restriction requirement. Moreover, Applicants submit that the sub-group restrictions are moot as all the claims and SEQ IDs recited by the Examiner have been cancelled. As explained below for the Examiner's convenience, there is no basis in law for the Examiner to maintain such sub-group restrictions in light of the cancellation of the claims reciting the identified species. Also presented below is an explanation of why the Examiner's 840-way restriction is overly burdensome and improper under the law.

A. There Is No Legal Basis For Restriction Based on Claims that are Not Present

The statutory basis that allows claims to be restricted is found in 35 U.S.C. 121. This section, however, only allows restriction of distinct inventions **that are claimed**. The text of 35 U.S.C. 121 is as follows:

> If two or more independent and distinct inventions **are claimed** in one application, the Director may require the application to be restricted to one of the inventions. ...

The MPEP 808 repeats the requirement from 35 U.S.C. 121 that restriction requirements must be based on what is claimed:

> **MPEP 808 Reasons for Insisting Upon Restriction**
>
> Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention *as claimed* is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the Examiner if restriction is not required ... (*emphasis in original*)

Notably, the text in part (A) of MPEP 808 puts the "as claimed" language in italics, making it clear that what is actually claimed cannot be ignored.

In this case, since the claims that trigged the sub-group restriction have been cancelled, there is no legal basis for maintaining the sub-group restrictions. As such, Applicants respectfully request that the sub-group restrictions be withdrawn.

B. The Examiner's 840-Way Restriction is Overly Burdensome

Applicants submit that a 840-way restriction requirement is overly burdensome, and not what was intended by Congress under 35 U.S.C. 121. This is not a case where 840 different, unrelated nucleic acid sequences are being claimed which might potentially justify a 840-way restriction. Instead, the originally filed claims, as noted by the Examiner, were directed to four different inventions, including three general methods and one general kit. A 4-way restriction would be keeping with the historical practices of the U.S. Patent Office, which has routinely examined general method claims along the line of those presented here. As such, this is an additional reason Applicants respectfully request that the sub-group restrictions be withdrawn.

C. The Examiner's Sub-Group Restrictions Were Not Proper

Applicants respectfully submit that the Examiner's initial sub-group restrictions were not proper and are hereby traversed. In particular, Applicants submit that the requirements under MPEP 808 have not been met as the Examiner has not explained: 1) why each invention as claimed is independent or distinct from the others and 2) the reasons why there would be a serious burden on the Examiner if the restriction were not required.

i. No Explanation of Why the Species Independent and Distinct

The first requirement under MPEP 808 for insisting upon a restriction is "(A) the reasons (as distinguished from the mere statement or conclusion) why each invention as claimed is either independent or distinct from the others." In the Restriction Requirement, the Examiner grouped all three sub-groups and provided the following reasons for alleging independence of all 18 species in the sub-groups:

> "In the instant case the each [sic] of the different ligases, RNA polymerases, promoters and analytes are structurally independent and distinct molecules capable of separate manufacture, and use." (Office Action, page 4).

The Examiner's rationale, however, fails to look at "each invention as claimed," as required under MPEP 808. The Applicants are claiming **methods** that employs an *RNA polymerase*, a *ligase,* and a *promoter* - Applicants are not claiming **compositions** comprising the 18 species in the 3 sub-groups. Therefore, the fact that all of the species are capable of separate manufacture and use is irrelevant to these method claims. In other words, in most biotech type methods with multiple components, the components are generally capable of separate manufacture and use. Therefore, the first prong of MPEP 808 has not been met by the Examiner, making the sub-group restrictions improper under the law.

It is further noted that the rationale provided by the Examiner would *never* allow a general method claim to be Examined by the Patent Office, and could always be used (if valid) to restrict such general methods into hundreds or thousands of different inventions. This is not consistent with the law as implemented under MPEP 808 and is not consistent with the historical or current practices of the U.S. Patent Office.

ii. No Search Burden Exists

The second requirement under MPEP 808 for insisting upon a restriction is "(B) the reasons why there would be a serious burden on the examiner if restriction is not required." Under MPEP 808.02 the Examiner can show a serious burden by showing one of the following: (a) separate classification, (b) a separate status in the art when they are classifiable together; or (c) a different field of search. In this case, the Examiner recites a conclusory statement (relying on the faulty distinctiveness logic discussed above) without attempting to explain *why* there would be a serious burden if the 840-way restriction were not imposed:

> "Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper." (Office Action, page 5).

This collection of "reasons" is simply conclusory and therefore not sufficient. The Examiner never discusses how or why any of the species have a separate status in the art, nor does he point to any evidence. The Examiner never discusses the classification of any of the species, so he is unable to state that they are different. Finally, the Examiner never discusses how or why the search for one species is different from the other species, nor does he provide evidence. As the Examiner has failed to provide any evidence, as required, to show that a search burden exists, the second prong of 808 is not met. This is a second and independent reason that the Examiner's sub-group restriction is improper and should be withdrawn.

III. Provisional Election

While Applicants believe that there is no legal basis for the Examiner maintaining the sub-group restrictions, Applicants provide an election to 1 of the 840 groups offered by the Examiner only because this is required under 35 U.S.C. 121 to maintain the right to petition, and as necessary, Appeal any final holding of restriction. The Applicants elect, with traverse, 1) Ampligase® Thermostable DNA ligase, 2) T7-type RNA polymerase; and 3) SEQ ID NO:16 for the promoter.

IV. Conclusion

In light of the above, Applicants respectfully request that the sub-group restrictions be withdrawn. If the Examiner wishes to discuss this case, Applicants encourage the Examiner to call the undersigned at 608-218-6900 at the Examiner's convenience.

Dated: 11/13/06

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